Table 1: Summary by types of incontinence\*

## Decision Memo for Biofeedback for Urinary Incontinence (CAG-00020N)

## **Decision Summary**

Amend Coverage Issues Manual 35-27 to include the following:

Biofeedback therapy is covered for the treatment of stress and/or urge incontinence in patients who failed a documented trial of pelvic muscle exercise training or who are unable to perform pelvic muscle exercises. Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

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## **Decision Memo**

To: File: Biofeedback for Treatment of Urinary Incontinence

CAG-00020N

From:

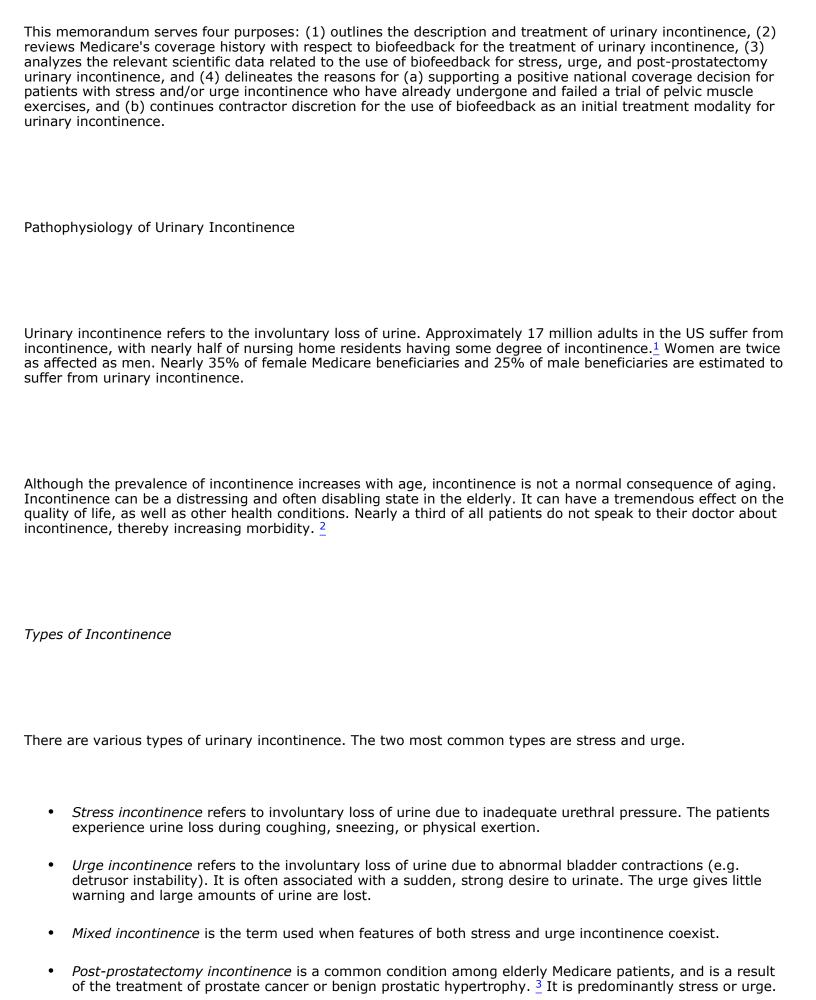
Sean R. Tunis, M.D., M.Sc. Director, Coverage and Analysis Group

Anthony Norris, MPA Health Insurance Specialist

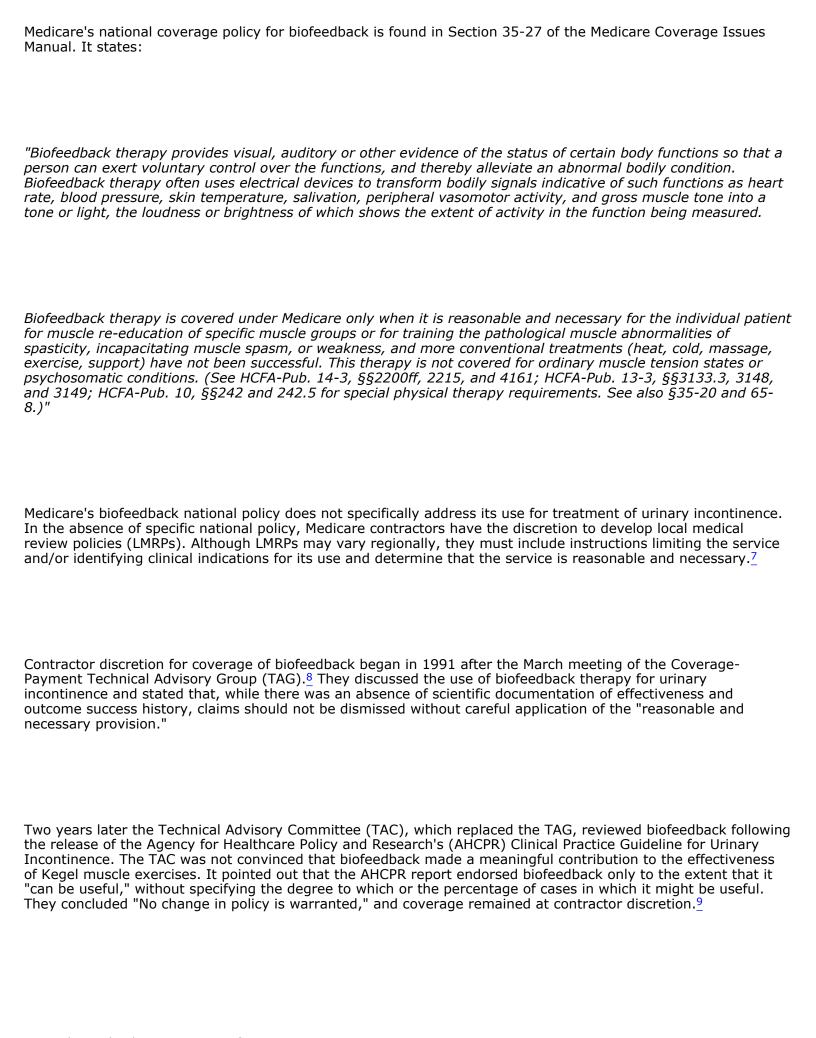
Kenneth Simon, M.D. Medical Officer, Coverage and Analysis Group

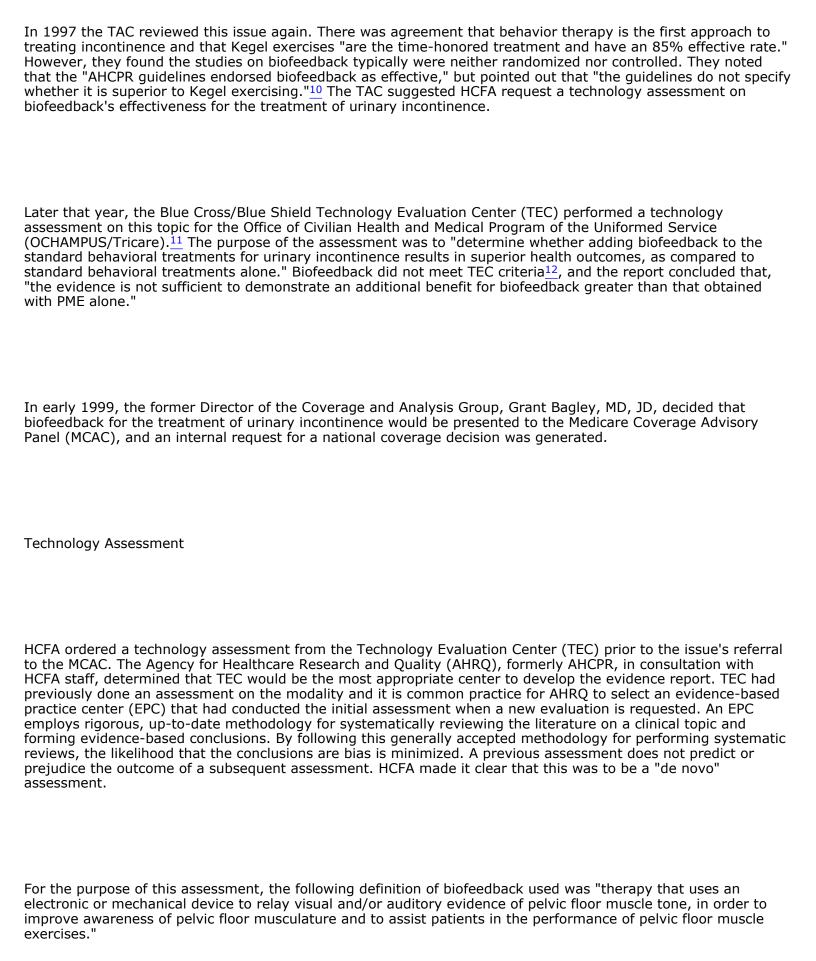
Re: National Coverage Decision

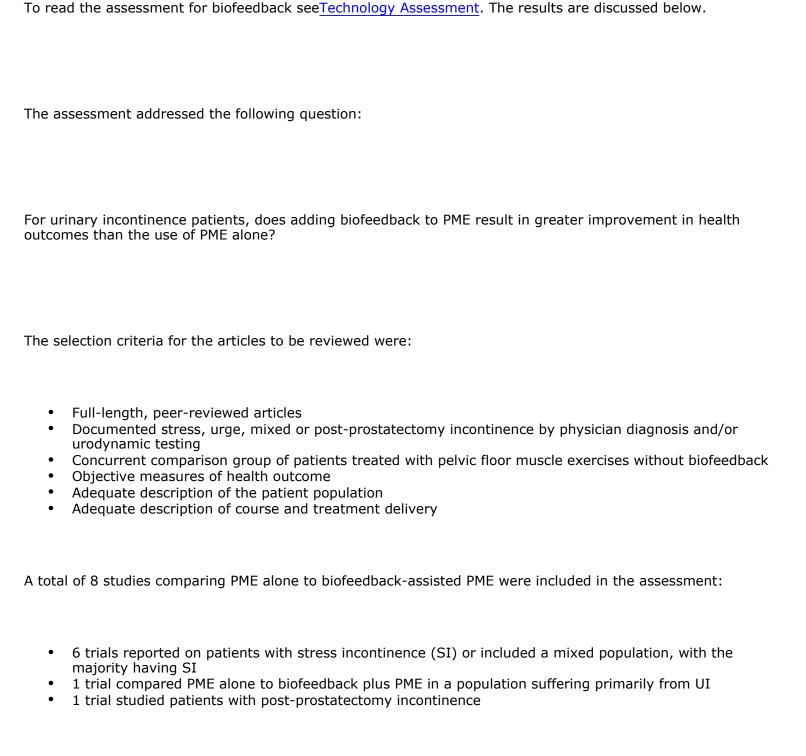
Date: October 6, 2000











The breakdown of the studies can be seen in Table 1.

Stress Incontinence	Urge Incontinence	Post-prostatectomy Incontinence
6 studies (4 randomized) (n=321)		1 randomized study (n=30)

n=number of patients

<sup>\*</sup>this represents articles in the technology assessment only, and does not include articles in the exclusion tables, or articles received after the Medicare Coverage Advisory Committee (MCAC) meeting

Six articles on SI met the inclusion criteria for the TEC assessment. These studies were relatively small, with the largest including approximately 40 patients in each arm. Blinding was reported in 2 studies, and 4 studies reported some form of randomization. Overall, 3 trials reported no significant differences between groups on the outcomes of interest (Ceresoli et al. 1993, Burns et al. 1993, and Berghmans et al. 1996). Three trials (Burgio et al. 1986, Glavind et al. 1986, and Shepherd et. al. 1983) reported a greater improvement in the biofeedback-assisted PME arm over the PME alone arm, with results in 2 studies being statistically significant. In Burgio et al. patients treated with biofeedback-assisted PME reported significant improvement in incontinent episodes (76% improvement vs. 51%, p<0.05). Glavind et al. reported also reported positive results. Standardized pad test outcomes were assessed at the end of a 4-week trial and 3-month follow up. The biofeedback group showed a greater percentage of improvement at each interval (72% vs. -48%) and (91% vs. 22%) respectively. Shepherd et. al. showed similar results (83% improvement vs. 25% but no statistical tests of significance were reported.

Of particular note is the Burns et al. study. The mean age of the 135 female participants was 63 years (range: 57-69 years), 34% of whom were age 65 and older, making the results particularly relevant to the Medicare population. In this study, there was no significant difference in percent improvement between the biofeedback-assisted PME and PME-alone groups (61% and 54% respectively) as compared to the waiting list control subjects.

Given the mixed results of the studies reviewed in the TEC assessment, as well as various methodologic limitations, it is impossible to draw definitive conclusions on whether the addition of biofeedback to PME improves outcomes as compared to PME alone. Five of the eight studies included showed the same improvement rate for PME alone as for PME with biofeedback. The statistically significant results reported Glavind et al. could be attributed to bias. Although the trial by Glavind et al. was randomized it is subject to both performance and attrition bias. There was greater treatment intensity in the biofeedback-assisted PME group and dropouts were greater in the PME alone group. The Burgio et al. study was not randomized.

For urge incontinence, a small study (Burton et. al. 1983, n=32) was identified, of which 26% of the patients were treated for SI. As with the Burns study, the age range (64-83 years) of the participants of this study allow inferences to the Medicare population. This nonrandomized study reported statistically significant improvement in frequency of incontinence for the biofeedback-assisted PME group and the PME alone group (79% and 82% respectively). This trial does not demonstrate a significant difference in percent improvement between the biofeedback-assisted PME and PME alone groups.

For post-prostatectomy incontinence, a single trial met the selection criteria (Franke et. al. 2000). This study randomized 30 patients, mean age 61.5 years, to a biofeedback-assisted PME arm and a usual care arm. It is unclear to what extent the control group was treated with PME. This group also received educational materials and follow up that may have included biofeedback. Both groups improved significantly over time; however, there was no difference between groups in magnitude of improvement.

The assessment made the following conclusions:

- Evidence is not adequate to draw conclusions on whether the addition of biofeedback to PME results in improved outcomes as compared to PME alone for stress incontinence.
- Evidence suggests that there is no additional benefit to the addition of biofeedback to PME for patients with urge incontinence.
- Evidence suggests that the addition of biofeedback to PME does not result in an additional benefit for patients with post-prostatectomy incontinence.

Additional Articles Not Included as Part of the Assessment

Seven additional articles were included for the MCAC panel to review. These studies are part of the "Exclusion articles" and were not included as part of the assessment described above. Although these articles were not part of the TEC assessment, they were reviewed by HCFA staff and sent to the MCAC for consideration. These articles did not directly address the assessment question, but met some inclusion criteria and were frequently cited by advocates of biofeedback. The Exclusion Tables [PDF, 61KB] provide details of these articles.

Medicare Coverage Advisory Panel

The Medical/Surgical Procedures Panel met to discuss the topic of biofeedback for the treatment of urinary incontinence on April 12, 2000. The panel included nationally recognized experts in health services research, a urologist and former president of the American Urological Association, a urogynecologist, an obstetrics/gynecologist, and a nurse expert in incontinence. The panel was sent the technology assessment, the exclusion tables, all articles, and a catalogue of additional materials received by the agency for the panel to review. This catalogue (which included such items as the AHCPR Guidelines on Urinary Incontinence, position statements by specialty societies, letters by individual physicians and patients) may be found in the Catalogue of Materials [PDF, 62KB].

Thirteen people spoke during the panel meeting, representing a cross section of providers and professional societies.

Upon completion of all testimony and committee deliberations, the panel was asked to vote on two questions. If the panel vote was affirmative on the first question, they were to proceed to question number 2. If the panel voted not to affirm any part of question 1, then they would not be able to proceed to answering question 2.
1. Is the scientific evidence adequate to draw conclusions about the effectiveness of biofeedback in routine clinical use for the following three indications:1) stress incontinence, 2) urge incontinence, and 3) post-prostatectomy incontinence in the Medicare populations?
The following points were to be considered when answering this question:
Is there evidence that the studies do not over or underestimate the effect of the intervention?
<ul> <li>Are the results of the studies consistent or are they contradictory?</li> <li>Are the results of the studies applicable to the Medicare population?</li> <li>Do the studies permit conclusions about the effects of the technology?</li> <li>Are the results likely to apply in the general clinical setting?</li> </ul>
2. If the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect of the addition of biofeedback to PME compared to PME alone? Please refer to the following seven categories in making this determination.
Categories of Effectiveness
Seven categories of effectiveness were presented:
<ul> <li>Breakthrough technology: The improvement in health outcomes is so large that the intervention becomes standard of care.</li> </ul>
More effective: The new intervention improves health outcomes by a significant, albeit small, margin as compared with established services or medical items.

- As effective but with advantages: The intervention has the same effect on health outcomes as established services or medical items but has some advantages (convenience, rapidity of effect, fewer side effects, other advantages) that some patients will prefer.
- As effective and with no advantages: The intervention has the same effect on health outcomes as established alternatives but with no advantages.
- Less effective but with advantages: Although the intervention is less effective than established alternatives (but more effective than doing nothing), it has some advantages (such as convenience, tolerability).
- Less effective and with no advantages: The intervention is less effective than established alternatives (but more effective than doing nothing) and has no significant advantages.
- Not effective: The intervention has no effect or has deleterious effects on health outcomes when compared with "doing nothing," (e.g., treatment with placebo or patient management without the use of a diagnostic test).

For question one, UI, SI, and post-prostatectomy incontinence were addressed individually. The results were:

- 8-2 that there was insufficient evidence to determine the effectiveness of biofeedback as adjunct to PME in routine clinical use in the Medicare populations for SI.
- 10-0 that there was insufficient evidence to determine the effectiveness of biofeedback as adjunct to PME in routine clinical use in the Medicare populations for UI.
- 10-0 that there was insufficient evidence to determine the effectiveness of biofeedback as adjunct to PME in routine clinical use in the Medicare populations for post-prostatectomy incontinence.

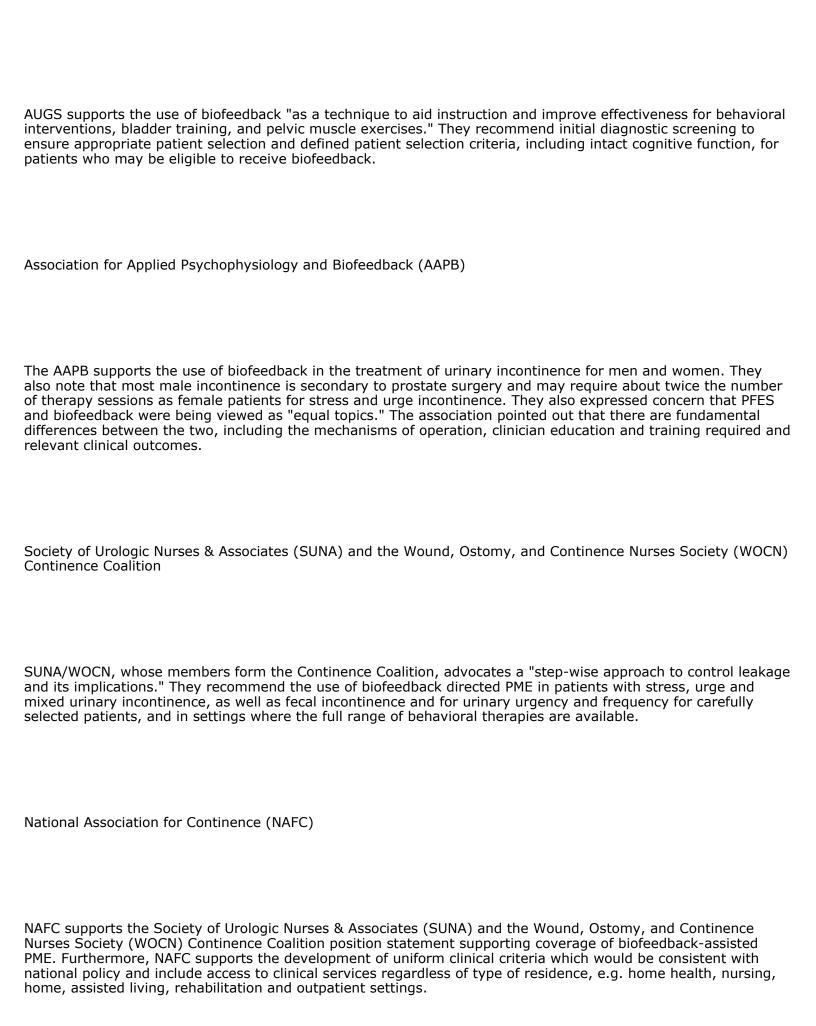
Since the panel found that there was insufficient evidence to determine the effectiveness of biofeedback, they did not proceed to the second question. However, several panel members commented that if they were to vote specifically on coverage, they would have voted yes. Some panel members noted that they felt the testimony of professional societies and experts could support a positive coverage decision.

The MCAC Executive Committee met and ratified the recommendations of the Medical/Surgical Procedures Panel on June 6. The chair of the Executive Committee submitted the decision to HCFA on July 25, 2000. Neither the Medical / Surgical panel nor the executive committee was asked to discuss the effectiveness of biofeedback when used in patients who have failed a trial of PME, or are unable to perform PME.

In the interim, HCFA continued to meet with clinical experts, professional societies, industry representatives, and other interested parties who wished to provide information to help in the decision process. The following is a brief summary of the national organizations' comments on the topic of biofeedback.

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American Urogynecologic Society (AUGS)



HCFA Analysis
In addition to the aforementioned technology assessment, articles not included in the assessment and recommendations of the MCAC, this analysis also takes into consideration the position statements of specialty societies, and all other information received by the agency on this topic.
The majority of studies reviewed showed no benefit of biofeedback over PME alone. The studies that found no significant difference in outcomes may have lacked sufficient power to detect group differences, or biofeedback may only be effective for a subset of patients, and this benefit may not be apparent when the entire group of patients is analyzed.
The AHCPR Guideline gave a Level A Recommendation to biofeedback-assisted PME for UI, SI, and mixed incontinence. However, the guideline focused on the use of biofeedback-assisted PME compared to nothing. HC did not ask that question. HCFA asked: Is biofeedback plus PME more effective than PME alone (which may or may not have included non-mechanical biofeedback)? The objective was to determine how much of the benefit due to PME alone and how much is due to the addition of biofeedback to PME. Consistent with the HCFA analys the AHCPR noted: "Further controlled studies are needed to demonstratethe conditions in which biofeedback provides an added benefit to PME alone."
The MCAC was unable to draw conclusions about the effectiveness of biofeedback from the scientific evidence presented. Conversely, the general consensus of the medical professional societies, clinical experts, consumers and others was that biofeedback adds significant benefit to patients learning to execute PMEs, and should be a covered treatment option.
Summary

The studies reviewed for biofeedback either showed conflicting results, as in the case of the six SI studies, or biofeedback was not shown to be superior to PME alone as in the case of urge incontinence and post-prostatectomy incontinence. Based strictly on the body of scientific evidence, it is not clear that biofeedback adds clinical benefit above and beyond PME alone. This contributed to the MCAC panel finding the scientific evidence presented inadequate to conclusively determine the effectiveness of the addition of biofeedback assisted PME compared to PME alone. Conversely, the professional societies' consensus statements, expert opinions, and additional analysis strongly asserted the value of biofeedback-assisted PME.

While the scientific evidence on the effectiveness of biofeedback was inconclusive, there were some studies that suggested clinical benefit from this intervention. In addition, clinical experts and professional organizations supported the use of biofeedback, based on positive clinical experience with the procedure. HCFA's conclusion based on this information is that coverage for biofeedback as initial therapy for UI should remain at the discretion of Medicare contractors. There is limited direct empirical evidence on whether biofeedback improves outcomes in patients who have failed PME or are unable to perform PME. Despite this, we felt that coverage in this situation was warranted, given the combination of suggestive scientific evidence and broad positive expert testimony. Further controlled clinical studies of this application of biofeedback would be of considerable value in clinical practice, and would confirm the appropriateness of this coverage policy.

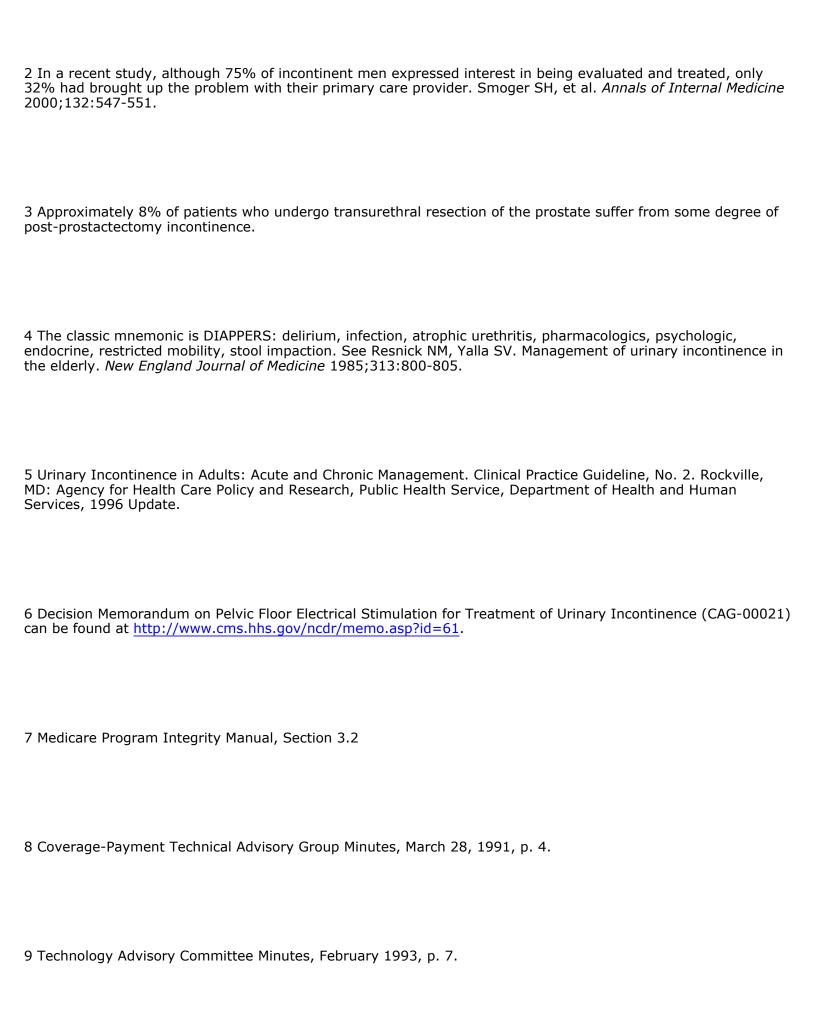
We encourage physicians, patients, manufacturers, and others to review the recent National Coverage Determination on Clinical Trials. The decision memo details the implementation of President Clinton's Executive Memorandum on covering routine patient care costs for Medicare patients enrolled in clinical trials.  $\frac{13}{2}$  Such provision of Medicare funding is designed to help the Medicare program answer questions about the effectiveness of therapies on Medicare patients. It would be particularly interesting to see a clinical trial comparing the multiple behavioral therapies against each other, as well as to surgery. We would be interested in looking at this therapy again within the next three years with the hope of developing a national coverage policy for patients as an initial therapy based on high quality, rigorously designed studies.

## DECISION:

Amend Coverage Issues Manual 35-27 to include the following:

Biofeedback therapy is covered for the treatment of stress and/or urge incontinence in patients who failed a documented trial of pelvic muscle exercise training or who are unable to perform pelvic muscle exercises. Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

1 Urinary incontinence is a leading cause of admission to nursing homes.



10 Technology Advisory Committee Minutes, May 1997, p. 20.
11 Lefevre FV. Biofeedback in the Treatment of Adult Urinary Incontinence. Chicago, IL: Blue Cross and Blue Shield Association, 1997.
12 The five criteria are (A) The technology must have final approval from the appropriate government regulatory codies. (B) The scientific evidence must permit conclusion concerning the effect of the technology on health outcomes. (C) The technology must be as beneficial as any established alternative. (E) The improvement must be attainable outside the investigational settings.
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